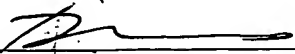




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Doran R. Pace, Patent Attorney

# INFORMATION DISCLOSURE STATEMENT

Examining Group 1646

Patent Application

Docket No. UF-243XD1

Serial No. 10/667,133

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1646  
Applicants : Howard M. Johnson, Mustafa G. Mujtaba  
Serial No. : 10/667,133  
Filed : September 19, 2003  
Conf. No. : 7182  
For : Materials and Methods for Inhibition of IgE Production

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.97 and §1.98, Applicants would like to bring to the attention of the Examiner, the references cited in the following patent application:

U.S. Serial No. 09/648,864, filed August 25, 2000.

The subject application, Serial No. 10/667,133, claims the benefit under 35 USC §120 of the filing date of the patent application Serial No. 09/648,864. Applicants respectfully request that the copies of references supplied in the Information Disclosure Statements of the 09/648,864 application, as well as references cited during the prosecution thereof, be made of record in the 10/667,133 application. As copies of the references filed in the 09/648,864 application, and cited on the attached form PTO/SB/08, can be found in the 09/648,864 casefile, copies of those references are not provided herewith.

Applicants have also listed on form PTO/SB/08 references which have not been cited in an Information Disclosure Statement of the 09/648,864 application. Copies of the references are enclosed with this Information Disclosure Statement. Applicants respectfully request that these references be made of record and considered in the examination of the subject application.

It is respectfully requested that the references cited in the 09/648,864 application be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



Doran R. Pace  
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Address: 2421 N.W. 41st Street, Suite A-1  
Gainesville, FL 32606-6669

DRP/ah  
Attachment: Form PTO/SB/08



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/667,133
Filing Date	September 19, 2003
First Named Inventor	Johnson, Howard M.
Art Unit	1646
Examiner Name	
Attorney Docket Number	UF-243XD1

Sheet 1 of 7

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	U1	US-5,906,286	05/25/1999	Soos <i>et al.</i>	All
	U2	US-5,939,286	08/17/1999	Johnson <i>et al.</i>	All
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F1	WO 99/20653	04/29/1999	Pepgen Corporation	All	
	F2	WO 97/39127	10/23/1997	University of Florida	All	
	F3	WO 97/33607	09/18/1997	Pepgen Corporation	All	
	F4	WO 96/28183	09/19/1996	Pepgen Corporation	All	
	F5	WO 94/10313	05/11/1994	University of Florida	All	
	F7					

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			Filing Date	September 19, 2003	
			First Named Inventor	Johnson, Howard M.	
			Group Art Unit	1646	
			Examiner Name		
Sheet	2	of	7	Attorney Docket Number	UF-243XD1

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	R1	BAZER, F.W. <i>et al.</i> "Effect of Ovine Trophoblast Protein-1 (oTP-1) on Replication of Feline (FIV) and Human (HIV) Immunodeficiency Viruses" <i>Biol. Reprod.</i> , 1989, Vol. 40, Suppl. 63.	
	R2	IMAKAWA, K. <i>et al.</i> "Interferon-like Sequence of Ovine Trophoblast Protein Secreted by Embryonic Trophoctoderm" <i>Nature</i> , 1987, pp. 377-379, Vol. 330.	
	R3	JOHNSON, H.M. <i>et al.</i> "How Interferons Fight Disease" <i>Sci. Am.</i> , 1994, pp. 68-75, Vol. 270, No. 5.	
	R4	SUBRAMANIAM, P.S. <i>et al.</i> "Differential Recognition of the Type I Interferon Receptor by Interferons $\tau$ and $\alpha$ is Responsible for Their Disparate Cytotoxicities" <i>Proc. Natl. Acad. Sci.</i> , 1995, pp. 12270-12274, Vol. 92.	
	R5	PONTZER, C.H. <i>et al.</i> "Structure/Function Studies with Interferon Tau: Evidence for Multiple Active Sites" <i>Journal of Interferon Research</i> , 1994, pp. 133-141, Vol. 14.	
	R6	DOLEN, J.G. <i>et al.</i> "Undetectable Interferon- $\alpha$ Serum Levels in a Patient with Atopic Dermatitis" <i>Journal of Interferon Cytokine Res.</i> , 1995, pp. 973-975, Vol. 15.	
	R7	SOOS, J.M. <i>et al.</i> "The IFN Pregnancy Recognition Hormone IFN- $\tau$ Blocks Both Development and Superantigen Reactivation of Experimental Allergic Encephalomyelitis Without Associated Toxicity" <i>J Immunol.</i> , 1995, pp. 2747-2753, Vol. 155.	
	R8	LACK, G. <i>et al.</i> "Nebulized IFN- $\gamma$ Inhibits the Development of Secondary Allergic Responses in Mice" <i>J Immunol.</i> , 1996, pp. 1432-1439, Vol. 157, No. 4.	
	R9	FINTER, N.B. <i>et al.</i> "The Use of Interferon- $\alpha$ in Virus Infections" <i>Drugs</i> , 1991, pp. 749-765, Vol. 42, No. 5.	
	R10	GRUSCHWITZ, M.S. <i>et al.</i> "Effects of Interferon-Alpha-2b on the Clinical Course, Inflammatory Skin Infiltrates and Peripheral Blood Lymphocytes in Patients with Severe Atopic Eczema" <i>Int. Arch. Allergy Immunol.</i> , 1993, pp. 20-30, Vol.101.	
	R11	WHALEY, A.E. <i>et al.</i> "Identification and Cellular Localization of Unique Interferon mRNA from Human Placenta" <i>J. Biol. Chem.</i> , 1994, pp. 10864-10868, Vol. 269, No. 14.	
	R12	HAMELMANN, E. <i>et al.</i> "Requirement for CD8 <sup>+</sup> T Cells in the Development of Airway Hyperresponsiveness in a Murine Model of Airway Sensitization" <i>J. Exp. Med.</i> , 1996, pp.1719-1729, Vol.183.	
	R13	KAY, A.B. <i>et al.</i> "Eosinophils and Neutrophils" <i>British Medical Bulletin</i> , 1992, pp. 51-64, Vol. 48, No. 1.	

Examiner Signature		Date Considered	
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			Filing Date	September 19, 2003	
			First Named Inventor	Johnson, Howard M.	
			Group Art Unit	1646	
			Examiner Name		
Sheet	3	of	7	Attorney Docket Number	UF-243XD1

NON PATENT LITERATURE DOCUMENTS			
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	R14	BAZER, F.W. <i>et al.</i> "Type I Conceptus Interferons: Maternal Recognition of Pregnancy Signals and Potential Therapeutic Agents" <i>Am. J. Reprod. Immunol.</i> , 1991, pp. 19-22, Vol. 26.	
	R15	HOFSTRA, C.L. <i>et al.</i> "Differential Effects of Endogenous and Exogenous Interferon- $\gamma$ on Immunoglobulin E, Cellular Infiltration, and Airway Responsiveness in a Murine Model of Allergic Asthma" <i>Am. J. Respir. Cell Mol. Biol.</i> , 1998, pp. 826-835, Vol. 19, No. 5.	
	R16	HAMELMANN, E. <i>et al.</i> "Allergen-Specific IgE and IL-5 are Essential for the Development of Airway Hyperresponsiveness" <i>Am. J. Respir. Cell Mol. Biol.</i> , 1997, pp. 674-682, Vol. 16.	
	R17	DAVIS, G.L. <i>et al.</i> "Treatment of Chronic Hepatitis C with Recombinant Interferon Alfa" <i>N. Engl. J. Med.</i> , 1989, pp. 1501-1506, Vol. 321, No. 22.	
	R18	QUESADA, J.R. <i>et al.</i> "Alpha Interferon for Induction of Remission in Hairy-Cell Leukemia" <i>N. Engl. J. Med.</i> , 1984, pp. 15-18, Vol. 310, No. 1.	
	R19	GODKIN, J.D. <i>et al.</i> "Purification and Properties of a Major, Low Molecular Weight Protein Released by the Trophoblast of Sheep Blastocysts at Day 13-21" <i>J. Reprod. Fert.</i> , 1982, pp. 141-150, Vol. 65.	
	R20	KASHIMA, H. <i>et al.</i> "Interferon Alfa-N1 (Wellferon) <sup>®</sup> in Juvenile Onset Recurrent Respiratory Papillomatosis: Results of a Randomized Study in Twelve Collaborative Institutions" <i>Laryngoscope</i> , 1988, pp. 334-340, Vol. 98, No. 3.	
	R21	MANCINO, D. <i>et al.</i> "Adjuvant Effects of Amorphous Silica and of Aluminium Hydroxide on IgE and IgG <sub>1</sub> Antibody Production in Different Inbred Mouse Strains" <i>Int. Archs. Allergy Appl. Immun.</i> , 1980, pp.253-258, Vol. 61.	
	R22	REVOLTELLA, R. <i>et al.</i> "Preferential Production of Rabbit Reaginic Antibodies" <i>Int. Arch. Allergy</i> , 1969, pp. 282-289, Vol. 36.	
	R23	MIGUEL, N.M.R. <i>et al.</i> "Effect of Aluminium Hydroxide Gel on the Secondary Response in Mice" <i>Int. Archs. Allergy Appl. Immun.</i> , 1977, pp. 382-384, Vol. 54.	
	R24	BECK, L. <i>et al.</i> "The Polyclonal and Antigen-Specific IgE and IgG Subclass Response of Mice Injected with Ovalbumin in Alum or Complete Freund's Adjuvant" <i>Cellular Immunol.</i> , 1989, pp. 1-8, Vol. 123.	
	R25	NILSSON, K. <i>et al.</i> "Established Immunoglobulin Producing Myeloma (IgE) and Lymphoblastoid (IgG) Cell Lines From an IgE Myeloma Patient" <i>Clin. Exp. Immunol.</i> , 1970, pp. 477-489, Vol. 7.	

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			Filing Date	September 19, 2003	
			First Named Inventor	Johnson, Howard M.	
			Group Art Unit	1646	
			Examiner Name		
Sheet	4	of	7	Attorney Docket Number	UF-243XD1

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	R26	ROTHMAN, P. <i>et al.</i> "Mitogen Plus Interleukin 4 Induction of C $\epsilon$ Transcripts in B Lymphoid Cells" <i>J. Exp. Med.</i> , 1988, pp. 2385-2389, Vol. 168.	
	R27	WEI, C.F. <i>et al.</i> "Isolation and Comparison of Two Molecular Species of the BAL 31 Nuclease from <i>Alteromonas espejiana</i> with Distinct Kinetic Properties" <i>J. Biol. Chem.</i> , 1983, pp. 13506-13512, Vol. 258, No.22.	
	R28	BONNEM, E.M. <i>et al.</i> "Interferon- $\alpha$ : Current Status and Future Promise" <i>J. Biol. Response Modifiers</i> , 1984, pp. 580-598, Vol. 3, No. 6.	
	R29	LANZAVECCHIA, A. <i>et al.</i> "In vitro Stimulation of IgE Production at a Single Precursor Level by Human Alloreactive T Helper Clones" <i>Clin. Exp. Immunol.</i> , 1984, pp.197-203, Vol. 55.	
	R30	WARNER, N.L. <i>et al.</i> "Immunoglobulin Classes in Antibody Responses in Mice I. Analysis By Biological Properties" <i>Immunology</i> , 1968, pp. 725-734, Vol. 14.	
	R31	BENOIT, P. <i>et al.</i> "A Monoclonal Antibody to Recombinant Human IFN- $\alpha$ Receptor Inhibits Biological Activity of Several Species of Human INF- $\alpha$ , IFN- $\beta$ , and IFN- $\omega$ " <i>Journal of Immunology</i> , 1993, pp. 707-716, Vol. 150, No. 3.	
	R32	COFFMAN, R.L. <i>et al.</i> "B Cell Stimulatory Factor-1 Enhances the IgE Response of Lipopolysaccharide-Activated B Cells" <i>Journal of Immunology</i> , 1986, pp. 4538-4541, Vol. 136, No. 12.	
	R33	COFFMAN, R.L. <i>et al.</i> "A T Cell Activity That Enhances Polyclonal IgE Production and Its Inhibition by Interferon- $\gamma$ " <i>Journal of Immunology</i> , 1986, pp.949-954, Vol. 136, No.3.	
	R34	MUJTABA, M.G. <i>et al.</i> "IFN- $\tau$ Suppresses Both the Autoreactive Humoral and Cellular Immune Responses and Induces Stable Remission in Mice with Chronic Experimental Allergic Encephalomyelitis" <i>Cellular Immunology</i> , 1998, pp. 94-102, Vol. 186.	
	R35	SOOS, J.M. <i>et al.</i> "Oral Feeding of Interferon $\tau$ Can Prevent the Acute and Chronic Relapsing Forms of Experimental Allergic Encephalomyelitis" <i>Journal of Neuroimmunology</i> 1997, pp. 43-50, Vol. 75.	
	R36	MUJTABA, M.G. <i>et al.</i> "CD4 T Suppressor Cells Mediate Interferon Tau Protection Against Experimental Allergic Encephalomyelitis" <i>Journal of Neuroimmunology</i> , 1997, pp. 35-42, Vol. 75.	
	R37	PONTZER, C.H. <i>et al.</i> "Antiproliferative Activity of a Pregnancy Recognition Hormone, Ovine Trophoblast Protein-1" <i>Cancer Research</i> , 1991, pp. 5304-5307, Vol. 51.	

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	R38	MUJTABA, M.G. <i>et al.</i> "IFN- $\gamma$ Inhibits IgE Production in a Murine Model of Allergy and in an IgE-Producing Human Myeloma Cell Line" <i>J Allergy Clin Immunol</i> , 1999, pp. 1037-1044, Vol. 104, No. 5.		
	R39	MUJTABA, M.G. <i>et al.</i> "IFN- $\gamma$ Inhibits IgE Production in a Murine Model of Allergy and in an IgE-Producing Human Myeloma Cell Line" <i>FASEB Journal</i> , 1999, Vol. 13, No. 4, A337, XP-000943709, abstract only.		
	R40	KIMATA, H. <i>et al.</i> "Interferon-alpha Treatment for Severe Atopic Dermatitis" <i>Allergy</i> , 1995, pp. 837-840, Vol. 50.		
	R41	SAVELKOUL, H.F.J. <i>et al.</i> "Regulation of In Vivo IgE Responses by IL-4 and IFN- $\gamma$ " <i>Journal of Cellular Biochemistry Suppl.</i> , 1993, p. 118, XP-000943455, abstract only.		
	R42	CHEN, Y.L. <i>et al.</i> "Mosquito Allergy: A Mouse Model for Study of Antigen-Specific IgE and IgG Subclass Responses, Lymphocyte Proliferation, and IL-4 and IFN- $\gamma$ Production" <i>Journal of Allergy and Clinical Immunology</i> , 1998, Vol. 101, Supp. 158.		
	R43	WANG, H. <i>et al.</i> "Role of Interleukin-4 and Interferon- $\gamma$ in Pathogenesis of Asthma" <i>Chemical Abstracts</i> , 1999, Vol. 130, No. 13, p. 529, Columbus, Ohio, US, Abstract No. 166970u		
	R44	DUSHEIKO, G. M. <i>et al.</i> "Recombinant Leucocyte Interferon Treatment of Chronic Hepatitis B" <i>Journal of Hepatology</i> , 1986, pp. S199-S207, Vol. 3, Supp. 2, Elsevier Science Publishers Biomedical Division.		
	R45	KHAN, O. A. <i>et al.</i> "Immunomodulating Functions of Recombinant Ovine Interferon Tau: Potential for Therapy in Multiple Sclerosis and Autoimmune Disorders" <i>Multiple Sclerosis</i> , 1998, pp. 63-69, Vol. 4, Stockton Press.		
	R46	KIMATA, H. <i>et al.</i> "Interferon-Alpha Treatment for Severe Atopic Dermatitis" <i>Allergy</i> , 1995, pp. 837-840, Vol. 50.		
	R47	NOH, G. W. and LEE, K. Y. "Blood Eosinophils and Serum IgE as Predictors for Prognosis of Interferon-gamma Therapy in Atopic Dermatitis" <i>Allergy</i> , 1998, pp. 1202-1207, Vol. 53.		
	R48	PENE <i>et al.</i> <i>Proc. Natl. Acad. Sci. USA</i> , 1988, pp. 6880-6884, Vol. 85, No. 18.		
	R49	OLDHAM, ROBERT K. "Biologicals for Cancer Treatment: Interferons" <i>Hospital Practice</i> , 1985, pp. 71-91, Vol. 20, No. 12,		

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/667,133	
			Filing Date	September 19, 2003	
			First Named Inventor	Johnson, Howard M.	
			Group Art Unit	1646	
			Examiner Name		
Sheet	6	of	7	Attorney Docket Number	UF-243XD1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R50	HEEKE, GINO VAN <i>et al.</i> "High Yield Expression and Secretion of the Ovine Pregnancy Recognition Hormone Interferon - $\gamma$ by <i>Pichia pastoris</i> ", <i>Journal of Interferon and Cytokine Research</i> , 1996, pp. 119-126, Vol. 16.	
	R51	SOOS, JEANNE M. <i>et al.</i> "Type I Interferon Inhibition of Superantigen Stimulation: Implications for Treatment of Superantigen-Associated Disease", <i>Journal of Interferon and Cytokine Research</i> , 1995, pp. 39-45, Vol. 15.	
	R52	SUBRAMANIAM, P. <i>et al.</i> "Type I Interferon Induction of the Cdk-inhibitor p21 <sup>WAF1</sup> is Accompanied by Ordered G1 Arrest, Differentiation and Apoptosis of the Daudi B-cell Line", <i>Oncogene</i> , 1998, pp. 1885-1890, Vol. 16, Stockton Press.	
	R53	MCCONKEY, D. J. <i>et al.</i> "Signal Transduction Pathways in Apoptosis", <i>Stem Cells</i> , 1996, pp. 619-631, Vol. 14, AlphaMed Press.	
	R54	SOOS, J. M. <i>et al.</i> "Cutting Edge: Oral Type I IFN- $\gamma$ Promotes a Th2 Bias and Enhances Suppression of Autoimmune Encephalomyelitis by Oral Glatiramer Acetate", <i>The Journal of Immunology</i> , 2002, pp. 2231-2235, Vol. 169.	
	R55	GONGORA, R. <i>et al.</i> "Stat-1 Is Not Essential for Inhibition of B Lymphopoiesis by Type I IFNs" <i>The Journal of Immunology</i> , 2002, pp. 2362-2366, Vol. 165.	
	R56	BAZER, F.W. <i>et al.</i> "Type I Conceptus Interferons: Maternal Recognition of Pregnancy Signals and Potential Therapeutic Agents", <i>American Journal of Reproductive Immunology</i> , 1991, pp. 19-22.	
	R57	YANAI, Y. <i>et al.</i> "The Anti-Tumor Activities of Interferon (IFN)- $\alpha$ in Chronic Myelogenous Leukaemia (CML)-Derived Cell Lines Depends on the IFN- $\alpha$ Subtypes", <i>Cancer Letters</i> , 2002, pp. 173-179, Vol. 185.	
	R58	BARNES, B. <i>et al.</i> "On the Role of IRF in Host Defense", <i>Journal of Interferon and Cytokine Research</i> , 2002, pp. 59-71, Vol. 22.	
	R59	BRIERLEY, M. M. <i>et al.</i> "IFN- $\alpha/\beta$ Receptor Interactions to Biologic Outcomes: Understanding the Circuitry", <i>Journal of Interferon and Cytokine Research</i> , 2002, pp. 835-845, Vol. 22.	
	R60	KOTENKO, S. V. <i>et al.</i> "IFN- $\lambda$ s Mediate Antiviral Protection Through a Distinct Class II Cytokine Receptor Complex", <i>Nature Immunology</i> , December 16, 2002, pp. 69-77, Vol. 4, No. 1.	
	R61	FASLER-KAN, E. <i>et al.</i> "Interferon- $\alpha$ Activates Signal Transducers and Activators of Transcription 5 and 6 in Daudi Cells", <i>Eur. J. Biochem.</i> , 1998, pp. 514-519, Vol. 254.	

Examiner Signature		Date Considered	
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	R62	ROGGE, L. <i>et al.</i> "The Role of Stat4 in Species-Specific Regulation of Th Cell Development by Type I IFNs", <i>The Journal of Immunology</i> , 1998, pp. 6567-6574, Vol. 161.	
	R63	RAMANA, C. V. <i>et al.</i> "Stat1-Dependent and -Independent Pathways in IFN- $\gamma$ -Dependent Signaling", <i>Trends in Immunology</i> , February 2002, pp. 96-101, Vol. 23, No. 2.	
	R64	LIN, SHIAW-YIH <i>et al.</i> "Nuclear Localization of EGF Receptor and its Potential New Role as a Transcription Factor", <i>Nature Cell Biology</i> , September 2001, pp. 802-808, Vol. 3.	
	R65		
	R66		
	R67		
	R68		
	R69		
	R70		
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	R72		
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